

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

In re Testosterone Replacement)	
Therapy Products Liability Litigation)	Case No. 14 C 1748
Coordinated Pretrial Proceedings)	MDL No. 2545
-----)	
(This document applies to all cases))	

CASE MANAGEMENT ORDER NO. 124
(Ruling on Besins defendants' motion for summary judgment, dkt. no. 2425)

MATTHEW F. KENNELLY, District Judge:

Some of the plaintiffs in this multidistrict litigation (MDL) proceeding who allege that they were injured as a result of taking AndroGel, a testosterone replacement therapy (TRT) drug, have sued defendants Besins Healthcare Inc. (Besins Inc.) and Besins Healthcare, S.A. (Besins S.A.) (collectively, the Besins defendants) for their alleged involvement in designing, manufacturing, or selling the drug. In September 2015, the Court dismissed six claims that plaintiffs conceded could not be properly asserted against the Besins defendants: strict liability—failure to warn; negligent misrepresentation; breach of implied warranty of merchantability; breach of express warranty; fraud; and consumer protection. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 136 F. Supp. 3d 968 (N.D. Ill. 2015). In that same decision, the Court denied the Besins defendants' motion to dismiss plaintiffs' claims for strict liability—design defect; negligence; redhibition; and claims seeking damages pursuant to those causes of action, including unjust enrichment. In October 2016, the Court denied Besins S.A.'s motion to dismiss all claims against it for lack of personal jurisdiction. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C

1748, MDL No. 2545, 2016 WL 5890022 (N.D. Ill. Oct. 10, 2016). And in May 2017, the Court granted the Besins defendants' motion for summary judgment on all claims asserted against them by Robert Rowley—one of the plaintiffs whose case has been selected for a bellwether trial and the only bellwether plaintiff to date to have sued the Besins defendants. *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, MDL No. 2545, Case Management Order No. 50 (May 8, 2017).

The Besins defendants have now moved for summary judgment against all plaintiffs in the MDL on the remaining claims against them. For the following reasons, the Court grants the motion.

Background

The following facts are undisputed unless otherwise noted. Besins S.A. is a privately held Belgian corporation with headquarters in Monaco. It co-developed the pharmaceutical formulation for AndroGel and has manufactured AndroGel at locations outside of the United States, including for sale in the United States. Besins S.A. has never marketed AndroGel in the United States. Rather, it has licensed to defendant AbbVie, Inc.—and, previously, to AbbVie's predecessor entities, defendants Unimed Pharmaceuticals, LLC and Solvay Pharmaceuticals, Inc.—the exclusive right to market and distribute AndroGel in the United States.

Besins S.A. maintains the worldwide pharmacovigilance database for AndroGel. The database contains all reported adverse events for AndroGel, including those from the United States. Besins S.A. has a pharmacovigilance department that, among other things, "[c]ollect[s] all safety information on [AndroGel] obtained from published literature, spontaneous case reports or clinical studies," "[e]nsure[s] timely expedited

reporting of adverse events," and evaluates AndroGel's "risk / benefit ratio through signal detection activities." Pls.' Opp., Ex. 5 at 7. Besins S.A. also has a global safety committee for Besins products that, among other things, analyzes safety signals, assesses "risk / benefit ratio[s]," *id.*, and decides whether to raise the possibility of "suspending the market authorisation of [a] Besins' [sic] product . . . to the Global Labelling Committee." *Id.*, Ex. 6 at 9.

In early 2013, Besins S.A. and AbbVie entered into a Safety Data Exchange Agreement (Safety Agreement) "for purposes of facilitating accurate, timely exchange of adverse events and each company's compliance with regulatory reporting requirements in each company's territories." *Id.*, Ex. 7 at 1. Each company is responsible for reporting "to the regulatory authorities within the territories where it is the Marketing Authorization Holder (MAH)." *Id.* at 3. AbbVie is the MAH in the United States and Besins S.A. is the MAH in territories outside of the United States. *Id.* at 15-16. Both Besins S.A. and AbbVie are "responsible for the detection and evaluation of safety signals" and for communicating to each other "any identified safety signal upon confirmation of the validity of the safety signal." *Id.* at 9. Besins S.A. had similar pharmacovigilance agreements with AbbVie's predecessor entities.

Jay Bua is the president and CEO of Besins Inc. He is on Besins S.A.'s board of directors and gave a 30(b)(6) deposition as Besins S.A.'s corporate representative. Bua testified during his deposition that Besins S.A. uses its pharmacovigilance database "[e]xclusively" "for ex-U.S. purposes" and that Besins S.A. does not "have any role in the reporting of adverse events or pharmacovigilance in the United States." Pls.' Opp., Ex. 1 at 103:12-104:22. That role "[is] maintained by AbbVie." *Id.* at 104:19-105:2.

Besins Inc. is a Delaware corporation with its principal place of business in Virginia. It is a wholly owned subsidiary of Besins S.A. Besins Inc. co-owns the AndroGel patent with AbbVie. It has never manufactured, sold, distributed, or promoted AndroGel and is not a party to the license or supply agreements between Besins S.A. and AbbVie. Besins Inc. is, however, responsible for the relationship with AbbVie in the United States. The parties dispute the extent of Besins Inc.'s responsibilities but agree that they include managing contract and patent issues.¹

Thomas MacAllister worked in research and development at a Besins subsidiary. From approximately 2004 to January 2015, he also served as special counsel for Besins Inc. In that capacity, he was primarily responsible for managing license and patent issues with AbbVie. In a June 2014 e-mail to Besins Inc. medical affairs employees, MacAllister discussed then-recent publications about purported cardiovascular (CV) risks associated with AndroGel. He wrote, among other things:

Objectively speaking there is not sufficient evidence on either side to draw a conclusion and the community should be calling for further study. Of course, that begs the question of who has the responsibility for that. The most obvious choice would be AbbVie and I suspect they are very well keeping their heads down to avoid this discussion. Derivatively, we are the second best candidate and we should be very careful too about getting into this discussion. Our company has also benefited financially along with AbbVie and I can easily see the discussion turning towards some kind of ethical obligation to society on the parts of those who have benefited to support addressing an important (and expensive) safety concern.

¹ The Besins defendants argue that "summary judgment is required for Besins Inc. because it played no role in the design, manufacture, and/or marketing of AndroGel." Defs.' Mot. at 4. Because summary judgment in favor of the Besins defendants is appropriate for other reasons, the Court need not address this argument. Similarly, the parties dispute the role, if any, that the Besins defendants play in AbbVie's marketing activities. This dispute is immaterial because plaintiffs have already conceded to dismissal of claims against the Besins defendants based on allegations of improper promotion or failure to warn.

Pls.' Opp., Ex. 14 at 1. When asked during his deposition whether he "believe[d] that any of the Besins entities owed an obligation to make sure that the product that was being sold in the U.S., AndroGel, did not carry the CV risks that were being purported in the studies," MacAllister testified during his deposition that the Besins defendants have no right to conduct safety studies in the United States. Pls.' Opp., Ex. 2 (MacAllister Dep.) at 162:18-163:9; *see also id.* at 163:7-9 ("This is AbbVie's product. And you know, if we wanted to run that study in the U.S., it would not be our choice."). He also testified, "We licensed the product to AbbVie while it was in formulation." *Id.* at 163:13-14.

Besins Healthcare² is listed as a TRT sponsor of an "industry briefing book" submitted to the FDA before a September 2014 Advisory Committee meeting. Defs.' Reply at 7. The meeting's topics included TRT's indication, prescription guidelines, and purported risks and benefits. Plaintiffs contend, and the Besins defendants deny, that the Besins defendants contributed to the briefing book. The parties agree that in connection with the Advisory Committee meeting, the Besins defendants hosted an event in Virginia for U.S.-based key opinion leaders (KOLs), or testosterone experts. Bua attended the KOL meeting, as did two Besins employees who are responsible for medical affairs and pharmacovigilance outside of the United States.

The Besins defendants meet periodically with AbbVie regarding AndroGel U.S. sales. Between 2010 and 2015, the Besins defendants received approximately \$398 million in royalties from AndroGel U.S. sales. These royalties account for approximately

² The parties have not specified whether "Besins Healthcare" in this context refers to Besins S.A., Besins Inc., or both.

twenty-eight to thirty percent of the Besins defendants' revenues.

Discussion

Summary judgment is appropriate where there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. Civ. P. 56(a). A genuine dispute exists only if the evidence would allow a reasonable jury to return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "To survive summary judgment, the nonmoving party must show evidence sufficient to establish every element that is essential to its claim and for which it will bear the burden of proof at trial." *Diedrich v. Ocwen Loan Servicing, LLC*, 839 F.3d 583, 591 (7th Cir. 2016). In determining whether the non-moving party has presented sufficient evidence, courts view the record in the light most favorable to the non-moving party. *Id.*

1. Strict Liability—Design Defect

The Besins defendants argue that plaintiffs have not provided any specific facts or any expert testimony to demonstrate that there is any defect in AndroGel's design. Instead, the Besins defendants contend, plaintiffs rely on conclusory allegations that AndroGel "contained a defective condition because the design was defective and unsafe in that [it] caused serious injuries and death." Defs.' Mot. at 7 (quoting Fourth Am. Compl. ¶ 470). The Besins defendants also emphasize that when they moved for summary judgment in Rowley's case, Rowley conceded that he lacked evidence to support a claim for strict liability design defect against Besins S.A. Rowley also conceded that he lacked evidence to support *any* claim against Besins Inc. According to the Besins defendants, plaintiffs have not identified any new facts regarding an

alleged design defect since that time. Finally, the Besins defendants acknowledge that state-specific requirements differ for proving a strict liability design defect claim, but they argue that under the law of every state that recognizes such a claim, evidence of an actual defect is necessary. The Besins defendants contend that because plaintiffs have provided no such evidence, summary judgment in their favor is appropriate as to all plaintiffs in the MDL.

Plaintiffs do not dispute the Besins defendants' argument that regardless of the applicable state law, evidence of an actual defect is necessary to prevail on a claim for strict liability design defect. The Court thus considers plaintiffs to have conceded this point. In response to the Besins defendants' contention that plaintiffs have proffered no evidence of any actual defect in AndroGel, plaintiffs rely exclusively on the allegations in their complaint and on this Court's September 2015 order on the Besins defendants' motion to dismiss. There, in declining to dismiss the strict liability design defect claim, the Court stated:

The master complaint contains detailed allegations about the health hazards and risks of TRT drugs (including the formation of blood clots and other cardiovascular injuries), as well as the mechanism by which TRT drugs create those risks. Plaintiffs' complaint thus provides much more than 'bare allegation[s] that the [product] suffered from a 'design defect,' . . . or allegations that 'never even identif[y] what the supposed defect' is.

In re Testosterone Replacement Therapy Prods. Liab. Litig., 136 F. Supp. 3d 968, 977 (N.D. Ill. 2015) (citations omitted). Plaintiffs contend that this statement, along with one other sentence in the Court's order that paraphrases plaintiffs' allegations, establish that there is a genuine issue of material fact on the strict liability design defect claim.

Plaintiffs also argue that the Court should deny the Besins defendants' motion because the Besins defendants "offer no new arguments" regarding why plaintiffs' claim should

fail. Pls.' Opp. at 5.

As the non-moving party, it is plaintiffs' burden to identify evidence to show why defendants are not entitled to judgment as a matter of law. *Diedrich*, 839 F.3d at 591. Because plaintiffs have provided nothing more than quotations from their complaint and from this Court's order denying the Besins defendants' motion to dismiss, they have not met their burden. See, e.g., *Estate of Davis v. Wells Fargo Bank*, 633 F.3d 529, 539 (7th Cir. 2011) ("Allegations are one thing, but to withstand the defendants' motion for summary judgment," plaintiff must provide "evidence of a triable issue of fact"); see also *McMillan v. Collection Prof'ls Inc.*, 455 F.3d 754, 760 (7th Cir. 2006) (summary judgment standard is "different and significantly more demanding" than that for Rule 12(b)(6)). Accordingly, the Court grants the Besins defendants' motion for summary judgment on the strict liability design defect claim as to all plaintiffs in the MDL proceeding.³

2. Negligence

Plaintiffs contend that the Besins defendants are liable for negligence under a number of theories: design defect, manufacturing defect, failure to test, and failure to report adverse events. The Court addresses each theory in turn.

a. Design Defect and Manufacturing Defect

The Besins defendants argue that summary judgment in their favor is appropriate on plaintiffs' negligent design and manufacturing defect claims because regardless of

³ In light of this decision, the Court need not address the Besins defendants' argument that "[a]s a policy matter, Plaintiffs are generally precluded from bringing design defect claims in the pharmaceutical context because they involve the design of a molecule." Defs.' Mot. at 7.

differences in state law, plaintiffs must show the existence of an actual defect in AndroGel in order to prevail. They also suggest that plaintiffs cannot prevail on a negligent design defect claim in any state "without showing a feasible alternative design." Defs.' Mot. at 14. Plaintiffs do not dispute the Besins defendants' characterization of the legal requirements applicable to their negligent defect claims, so the Court again considers plaintiffs to have conceded the point. Similarly, plaintiffs present no evidence or argument that AndroGel suffers from a manufacturing defect. Thus the Court considers plaintiffs to have forfeited that negligence theory.

With respect to their negligent design defect theory, plaintiffs offer no evidence or argument other than that which they presented in support of their strict liability design defect claim. For the same reasons discussed above, plaintiffs cannot survive summary judgment with conclusory allegations and references to this Court's September 2015 order on the Besins defendants' motion to dismiss.

b. Failure to Test

Plaintiffs argue that the "Besins defendants knew that inadequate testing has been done regarding [CV] and [venous thromboembolism (VTE)] risks associated with AndroGel" and that they "knew or should have known that patients would foreseeably suffer injuries as a result." Pls.' Opp. at 7. According to plaintiffs, MacAllister's June 2014 e-mail establishes the Besins defendants' knowledge. And the Besins defendants had notice of the number of U.S. patients at risk, plaintiffs argue, because they received reports about U.S. sales of AndroGel at their meetings with AbbVie. Additionally, plaintiffs state that Besins S.A. designed and developed AndroGel; manufactures AndroGel for distribution in the United States; and has pharmacovigilance obligations

under the Safety Agreement, including to "evaluate[] reports of adverse events for AndroGel from all over the world." *Id.* at 6-7. Finally, plaintiffs argue that Besins Inc. is liable for the alleged failure to test because it co-owns the AndroGel patent and manages the relationship with AbbVie in the United States.

In response, the Besins defendants argue that they have no contractual "right to run studies of [AndroGel] in the United States" and that "Besins licensed AndroGel to AbbVie while the product was still in formulation." Defs.' Reply at 13 (citing MacAllister Dep. at 163:5-14). They also emphasize that plaintiffs have "fail[ed] to point to any specific action by Besins" that supports their claim. *Id.*

To prevail on a negligence claim, a plaintiff typically must prove that a defendant owes it a duty, that defendant breached the duty, and that the breach proximately caused plaintiff's injury. *See, e.g., Ennenga v. Starns*, 677 F.3d 766, 777-78 (7th Cir. 2012). The Court concludes that plaintiffs have not identified a genuine factual dispute on each element of their negligent failure to test claim. *See Diedrich*, 839 F.3d at 591. First, plaintiffs have provided nothing to support a contention that the Besins defendants have a duty to conduct safety studies in the United States. To the contrary, the undisputed evidence shows that the Besins defendants *cannot* do so, and plaintiffs have not attempted to reconcile that evidence with their position. With respect to non-U.S. territories, the Safety Agreement contemplates that Besins S.A. conducts clinical trials, collects data from the trials, and reports adverse events to AbbVie. But plaintiffs have not provided any evidence that shows the source or the scope of Besins S.A.'s testing obligations under foreign regulatory regimes or otherwise. Second, even assuming Besins S.A. has a duty to test outside of the United States, plaintiffs have not

provided any evidence from which a reasonable jury could find a breach of this duty. Plaintiffs rely on MacAllister's e-mail, but in isolation, the e-mail shows only that in June 2014, MacAllister wanted Besins S.A. to "be very careful . . . about getting into [the] discussion" about CV safety studies. Ex. 14 to Pls.' Opp. Plaintiffs have provided no evidence, for example, that Besins S.A. failed to conduct or fund safety studies or that it conducted inadequate safety studies.

Finally, plaintiffs have provided no evidence that the Besins defendants' alleged failure to test proximately caused plaintiffs' injuries. Plaintiffs' theory is that the Besins defendants' failure to adequately test AndroGel caused AbbVie to lack sufficient information about AndroGel's risks. The alleged failure to test, plaintiffs say, thus "directly contributed to AbbVie's failure to provide an adequate warning to healthcare providers in the United States." Pls.' Opp. at 8. Plaintiffs, however, do not cite any evidence to support this theory. Their conclusory argument is insufficient to withstand summary judgment. See, e.g., *Diedrich*, 839 F.3d at 591; *Estate of Davis*, 633 F.3d at 539.

c. Failure to Report Adverse Events

Plaintiffs also argue that the Besins defendants failed to report adverse events regarding AndroGel to AbbVie. They likewise contend that the Besins defendants "fail[ed] to communicate the risk of [CV] and VTE injuries with AndroGel to other TRT manufacturers, to testosterone experts in the United States, and to U.S. regulators at the FDA." Pls.' Opp. at 8. In support of these arguments, plaintiffs rely on much of the same evidence that they used for their failure to test theory. Plaintiffs add that Besins Healthcare is identified as a TRT Sponsor in the briefing book for the September 2014

Advisory Committee meeting; the Besins defendants contributed to the briefing book; the Besins defendants sponsored a TRT-related KOL meeting; and Bua and Besins medical affairs employees attended the KOL meeting. Plaintiffs do not, however, provide any examples of any actual contribution by the Besins defendants to the briefing book or to the KOL meeting. Nevertheless, according to plaintiffs, the aforementioned evidence shows that the Besins defendants "participated in discussions that are at the heart of [p]laintiffs' case" but failed to communicate adverse event and risk information. Pls.' Opp. at 9. Plaintiffs then urge that the Besins defendants' alleged failure to report caused AbbVie to give inadequate warnings about AndroGel's purported risks to "healthcare providers in the United States." *Id.*

The Court concludes that plaintiffs have not identified genuine disputes of material fact on each element of their failure to report claim. *Diedrich*, 839 F.3d at 591. First, plaintiffs have identified no evidence supporting a contention that the Besins defendants have a duty to report adverse events to "other TRT manufacturers [or] testosterone experts." That aside, as the Besins defendants point out, "AbbVie has the sole responsibility for reporting adverse events to the appropriate authorities within the United States," including the FDA. Defs.' Reply at 11. Under the Safety Agreement, Besins S.A. does have a duty to report adverse events to AbbVie. But plaintiffs have not offered any evidence that Besins S.A. has breached that duty. Namely, they do not provide a single example of an adverse event or any other information that the Besins defendants failed to report. Nor do plaintiffs provide evidence from which a reasonable jury could find that the Besins defendants have, at any time, known more about AndroGel's alleged risks than AbbVie has. Finally, plaintiffs' conclusory argument that

the Besins defendants' alleged failure to report caused AbbVie to give inadequate warnings, and thus proximately caused plaintiffs' injuries, is insufficient for reasons already discussed.

Overall, there is no evidence from which a reasonable jury could infer that the Besins defendants negligently designed or manufactured AndroGel, negligently failed to test AndroGel, or negligently failed to report adverse events relating to AndroGel. The Court therefore grants summary judgment in favor of the Besins defendants on plaintiffs' negligence claim.

3. Redhibition

Plaintiffs whose claims arise under Louisiana law have brought a redhibition claim against the Besins defendants. In Louisiana, buyers are warranted "against redhibitory defects, or vices, in the thing sold." LA. CIV. CODE ANN. art. 2520. "A defect is redhibitory when it renders the thing useless, or its use so inconvenient that it must be presumed that a buyer would not have bought the thing had he known of the defect." *Id.* A defect is also redhibitory when "without rendering the thing totally useless, it diminishes its usefulness or its value so that it must be presumed that a buyer would still have bought it but for a lesser price." *Id.* "'Defect' as contemplated in article 2520 means a physical imperfection or deformity or a lacking of the necessary components or level of quality." *Cazaubon v. Cycle Sport, LLC*, 79 So. 3d 1063, 1065 (La. Ct. App. 2011) (citation omitted).

The Besins defendants argue that non-Louisiana jurisdictions characterize Louisiana's redhibition cause of action as one for breach of implied warranty. They then contend that the Court should grant summary judgment against plaintiffs on their

redhibition claim "for the same reasons" plaintiffs conceded at the motion to dismiss phase that "their breach of implied warranty claims could not be properly asserted against Besins." Defs.' Mot. at 9. In response, plaintiffs again point to the Court's order on the Besins defendants' motion to dismiss and note that although the Court dismissed the claim for breach of implied warranty, it did not dismiss the claim for redhibition. As discussed above, however, the fact that the Court previously denied a motion to dismiss a claim does not by itself establish that the claim should survive summary judgment.

Plaintiffs also argue that their "redhibition claim is more akin to [their] design defect claim" and that it should survive "[f]or the same reasons that [their] strict liability design defect claim should survive." Pls.' Opp. at 5. In light of plaintiffs' concession that their redhibition claim should rise and fall with their strict liability design defect claim—and because the Court has already ruled against plaintiffs on that claim—the Court grants summary judgment in favor of the Besins defendants on plaintiffs' redhibition claim. *See also, e.g. Sheridan v. Merck & Co.*, No. Civ. A. 02-2581, 2003 WL 22902622, at *2-3 & n.3 (E.D. La. Dec. 8, 2003) (granting summary judgment to defendants on plaintiffs' claim that drug was defective and unreasonably dangerous within the meaning of the Louisiana Products Liability Act (LPLA), and finding that even if not precluded by the LPLA, plaintiffs' redhibition claim would "not survive summary judgment because Plaintiff has failed to show proof of a defect").⁴

⁴ "Courts have interpreted the LPLA as preserving redhibition as a cause of action only to the extent the claimant seeks to recover the value of the product or other economic loss." *De Atley v. Victoria's Secret Catalogue LLC*, Nos. 2004-C-0661, 2004-C-0662, 876 So. 2d 112, 115 (La. Ct. App. 2004).

4. Unjust Enrichment and Other Damages

Plaintiffs have also brought an unjust enrichment claim against the Besins defendants. They argue that "under the laws of several states, unjust enrichment is a separate cause of action rather than a derivative claim like loss of consortium." Pls.' Opp. at 10. According to plaintiffs, therefore, their claim for unjust enrichment should survive summary judgment even if the rest of their claims do not. Plaintiffs also argue that the Besins defendants did not properly move for summary judgment on the unjust enrichment claim because they treated it as a derivative claim for damages.

The Court need not address whether unjust enrichment is a separate cause of action—or whether the Besins defendants did not properly move for summary judgment on the claim by failing to treat it as such—because plaintiffs have not identified a basis for relief on this claim that is distinct from their other claims. Instead, plaintiffs argue that the Besins defendants have been unjustly enriched because, despite their alleged knowledge of insufficient testing, they have decided not to "pursue additional safety studies" and have instead "continue[d] profiting off of AndroGel sales." Pls.' Opp. at 11. Plaintiffs also quote from the unjust enrichment claim in their complaint, which alleges unspecified "conscious wrongdoing" coupled with plaintiffs' "expec[tation] that TRT products were safe and medically effective." *Id.* at 10-11.

Because the Court has granted the Besins defendants' motion for summary judgment on plaintiffs' other claims, and because plaintiffs have not shown that there is a genuine issue of material fact regarding unjust enrichment under a different theory, the Court grants the Besins defendants' motion for summary judgment on plaintiffs' unjust enrichment claim. The Court likewise grants their motion for summary judgment

on the claims that seek damages pursuant to plaintiffs' other causes of action: wrongful death, survival, loss of consortium, and punitive damages.

Conclusion

For the foregoing reasons, the Court grants the Besins defendants' motion for summary judgment on all remaining claims by all plaintiffs in the MDL proceeding [dkt. no. 2425].



MATTHEW F. KENNELLY
United States District Judge

Date: May 29, 2018